

116TH CONGRESS  
2D SESSION

# H. R. 4764

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IN THE SENATE OF THE UNITED STATES

OCTOBER 1, 2020

Received

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## AN ACT

To reauthorize the Stem Cell Therapeutic and Research Act  
of 2005, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

## **1 SECTION 1. SHORT TITLE.**

This Act may be cited as the “Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2020” or the “TRANSPLANT Act of 2020”.

## 6 SEC. 2. REAUTHORIZATION OF THE C.W. BILL YOUNG CELL

## 7 TRANSPLANTATION PROGRAM.

8           (a) ADVISORY COUNCIL MEETINGS.—Subsection (a)  
9 of section 379 of the Public Health Service Act (42 U.S.C.  
10 274k) is amended by adding at the end the following new  
11 paragraph;

12               “(7) The Secretary shall convene the Advisory  
13               Council at least two times each calendar year.”.

## 14 (b) INCREASING COLLECTION.—

1       ing the second and third sentences in such subparagraph.  
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3           (c) PERIODIC REVIEW OF STATE OF SCIENCE.—Section  
4       379 of the Public Health Service Act (42 U.S.C.  
5       274k) is amended by adding at the end the following new  
6       subsection:

7           “(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

8               “(1) REVIEW.—Not less than every two years,  
9       the Secretary, in consultation with the Director of  
10      the National Institutes of Health, the Commissioner  
11      of Food and Drugs, the Administrator of the Health  
12      Resources and Services Administration, the Advisory  
13      Council, and other stakeholders, where appropriate  
14      given relevant expertise, shall conduct a review of  
15      the state of the science of using adult stem cells and  
16      birthing tissues to develop new types of therapies for  
17      patients, for the purpose of considering the potential  
18      inclusion of such new types of therapies in the Pro-  
19      gram.

20               “(2) RECOMMENDATIONS.—Not later than  
21      June 30, 2024, the Secretary shall—

22                   “(A) complete the second review required  
23      by paragraph (1); and

24                   “(B) informed by such review, submit to  
25      the Committee on Health, Education, Labor,

1           and Pensions of the Senate and the Committee  
2           on Energy and Commerce of the House of Rep-  
3           resentatives recommendations on the appro-  
4           priateness of the inclusion of new types of  
5           therapies in the Program.”.

6         (d) AUTHORIZATION OF APPROPRIATIONS.—Section  
7 379B of the Public Health Service Act (42 U.S.C. 274m)  
8 is amended by striking “\$33,000,000 for fiscal year 2015  
9 and \$30,000,000 for each of fiscal years 2016 through  
10 2020” and inserting “\$30,000,000 for each of fiscal years  
11 2021 through 2025”.

12 **SEC. 3. CORD BLOOD INVENTORY.**

13       Subsection (g) of section 2 of the Stem Cell Thera-  
14 peutic and Research Act of 2005 (42 U.S.C. 274k note)  
15 is amended to read as follows:

16       “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
17 carry out this section, there is authorized to be appro-  
18 priated \$23,000,000 for each of fiscal years 2021 through  
19 2025.”.

20 **SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDI-  
21 CINE.**

22       Section 402 of the Public Health Service Act (42  
23 U.S.C. 282) is amended by adding at the end the fol-  
24 lowing:

1        "(o) REGENERATIVE MEDICINE.—The Director of  
2 NIH shall, as appropriate, continue to consult with the  
3 directors of relevant institutes and centers of the National  
4 Institutes of Health, other relevant experts from such in-  
5 stitutes and centers, and relevant experts within the Food  
6 and Drug Administration, to further the field of regenera-  
7 tive medicine using adult stem cells, including autologous  
8 stem cells, therapeutic tissue engineering products, human  
9 cell and tissue products, human gene therapies, and ge-  
10 netically modified cells.”.

11 **SEC. 5. GAO REPORT ON REGENERATIVE MEDICINE WORK-**  
12                      **FORCE.**

13        Not later than 2 years after the date of enactment  
14 of this Act, the Comptroller General of the United States  
15 shall submit to the Committee on Health, Education,  
16 Labor, and Pensions of the Senate and the Committee on  
17 Energy and Commerce of the House of Representatives  
18 a report that assesses the national blood stem cell work-  
19 force, including those related to the C.W. Bill Young Cell  
20 Transplantation Program established under section 379 of  
21 the Public Health Service Act (42 U.S.C. 274k). The re-  
22 port shall include—

23                      (1) an overview of the current employment lev-  
24                      els, in both commercial and academic settings, for—

1                             (A) positions necessary for the collection  
2                             and transplantation of stem cell therapeutics,  
3                             including bone marrow and cord blood;

4                             (B) positions in the field of regenerative  
5                             medicine using adult stem cells and related to  
6                             product development; and

7                             (C) Federal funding for extramural stem  
8                             cell programs;

9                             (2) an overview of the current employment lev-  
10                             els in Federal stem cell programs, including the  
11                             scope of, staffing models of, and vacancies within  
12                             such programs;

13                             (3) the identification of gaps, if any, in the pro-  
14                             jected workforce capacity for—

15                             (A) positions described in paragraph  
16                             (1)(A); and

17                             (B) the field of regenerative medicine using  
18                             adult stem cells, including workforce gaps re-  
19                             lated to the development of new cellular thera-  
20                             pies using adult stem cells;

21                             (4) an overview of the availability of training  
22                             programs related to the development, refinement,  
23                             and utilization of adult stem cells, including training  
24                             on good manufacturing practices for such activities,  
25                             and the performance of such programs; and

- 1                         (5) recommendations, if any, for improving the  
2                         workforce capacity related to—  
3                             (A) the positions described in paragraph  
4                             (1)(A); or  
5                             (B) the field of regenerative medicine using  
6                         adult stem cells.

Passed the House of Representatives September 30,  
2020.

Attest:                     CHERYL L. JOHNSON,  
*Clerk.*